Supporting Statement A for

Generic Clearance for NIH Citizen Science and Crowdsourcing Projects (NIH)

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Extension

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ATTACHMENTS

Attachment 1: Sub-study template form

Attachment 2: Privacy Act Memo

Attachment 3: Published 30-day FRN

A. Justification

This extension will allow the continuation of projects for Agency researchers and program staff to test ideas more quickly, respond to the project's needs as they evolve, and incorporate feedback from participants for flexible, innovative research methods. Any collection under this umbrella is expected to be low in burden. Call for Participants was added to section A.2 to give a clearer view to users of the type of collections that may fall under this generic and does not go beyond the scope of the original use and is shown as another means of gathering information about resources.

A.1 Circumstances Making the Collection of Information Necessary

Section 413 (b) (3) of the Public Health Service Act, 42 U.S. Code § 285 gives NIH the authority to collect this information.

Pursuant to Section 402 of the American Innovation and Competitiveness Act (P.L. 114-329) federal agencies have broad authority to use crowdsourcing to advance agency missions and facilitate broader public participation in the innovation process. The purpose of this collection is to identify existing research, educational, operational, and project information from the public in order to share more widely with a range of audiences. These types of collections will further the legislation's purposes of "accelerating scientific research, increasing cost-effectiveness to maximize the return on taxpayer dollars, addressing societal needs, providing hands-on learning in STEM, and connecting members of the public directly to federal science missions and to each other."

Many federal and non-federal organizations are already using innovative citizen science and crowdsourcing tools to advance their missions. These tools are especially valuable where data are sparsely distributed or when projects rely on large datasets. Successful citizen science and crowdsourcing projects usually result from iteration of the design based on feedback from the participants. Also, there could be uncertainty about whether the time and effort to create a project will capture the interest of the public and yield meaningful public participation.

Citizen science and crowdsourcing are tools that engage, educate and empower the public to apply their curiosity and contribute their talents and feedback to a wide range of scientific and societal issues. Citizen Science is a form of open collaboration where the public can participate actively in the scientific process through methods that include asking research questions, collecting and analyzing data, interpreting results, or engaging in problem solving. Crowdsourcing is a process where individuals or organizations submit an open call for contributions of information from a group of individuals ("the crowd").

A.2 Purpose and Use of the Information Collection

The purpose of this information collection is to:

- Accelerate scientific research
- Increase cost-effectiveness to maximize the return on taxpayer dollars
- Address societal needs
- Provide hands-on learning in STEM education

- Connect members of the public directly to federal science missions and each other
- Identify and disseminate resources more broadly to the public, on the Institutes' and Centers' (ICs) websites, and/or
- Collect information for agency internal use to improve scientific practices and/or assist in scientific reviews

Citizen science and crowdsourcing collections under this generic clearance may include the following types of questions or requests of participants:

- **Personal and Contact Information.** Projects submitted under this generic clearance may solicit contact information. This information may be necessary to organize and analyze data. Projects may request contact information (name and email address, zip code, address and phone number) to provide participants with project updates and share data. Participants would be made aware that the publically available data on contact information will be anonymized and aggregated, for example, by census tract, zip code, city, or some other higher level than individual addresses.
- Names and Nominations. NIH relies on nominations to recruit appropriate scientific
 expertise, broaden membership of review panels, and receive recommendations for
 reviewers. Projects submitted under this generic clearance may include public
 solicitations for nominations, to include project overviews, request for abstracts, or
 relevant qualifying questions related to the reason for individual's nomination. This
 information would only be used by NIH internally to select eligible candidates from the
 scientific community.
- **Experience and Expertise.** For data quality purposes, projects submitted under this generic clearance may request information to evaluate the skill level of the participant by asking about their experience with the project topic. Questions may be about a person's age range, level or topic of education, participation in organizations, or professional experience.
- **Call for Participants.** Individuals representing a breadth of investigators and institutional representatives will be engaged by conducting listening sessions which are intended to inform future strategic planning, initiatives, and resources around health, research, and training across the NIH.
- Requests for population characteristics within crowdsourcing mechanisms, such as institutional affiliation and career level/stage. For example, this mechanism will allow for individuals interested in a certain topic to sign up for alerts that NIH may send in the future, and at the same time allows NIH to identify individuals interested in various topics with a goal to potentially contact them in the future.
- Identification or Descriptions of Extramural Research, Research Tools, or Existing Resources. Projects may include requests to identify and/or describe extramural research, research tools, or existing resources. This will allow NIH to identify best practices and developments within the scientific community that could inform future NIH program development. This could be a means to publicly identify emerging tools, guidance, or research or to review, vet, and encourage the use of public health interventions in the community and clinical settings. Making this information publicly available could enhance the quality, speed, and public health impact of efforts to translate research into practice. It will also help the agency understand resources availability in extramural or

other public environments. Existing resources collections will include accessing and requesting data. Data sharing allows data generated from one research study to be used to answer questions beyond the original study. It reinforces open scientific inquiry, encourages diversity of analysis, supports studies on data collection methods and measurement, facilitates the education of new researchers, and enables the exploration of topics not envisioned by the initial investigators. Biomedical researchers and data scientists may use a portals resources, web interface, and computational workspace to query, analyze, and visualize data.

Generic ICs under this clearance might include applications and registrations needed to access/request data however, it would not allow for programs to submit data. The applications or registrations may ask the requestor's credentials and a description of the proposed use of the data.

To obtain approval for a collection that meets the conditions of this generic clearance, a standardized form along with supporting documentation will be submitted to OMB along with any other supporting documentation.

There have been 86 projects approved under this clearance cycle with several programs wishing to continue to collect data past the current expiration date.

A.3 Use of Information Technology and Burden Reduction

If appropriate, programs will collect information electronically and/or use online collaboration tools to reduce burden. Screenshots will be provided for all online data collection instruments. A Privacy Impact Assessment (PIA) will be completed for all online requests.

A.4 Efforts to Identify Duplication and Use of Similar Information

No similar data are gathered or maintained by the agency or available from other sources known to the agency.

A.5 Impact on Small Businesses or Other Small Entities

Small business or other small entities may be involved in these efforts, but the agency will minimize the burden on them of information collections approved under this clearance by sampling, asking for readily available information, and using short, easy-to-complete information collection instruments.

A.6 Consequences of Collecting the Information Less Frequently

Forms will be submitted on an as needed basis.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances. The information collected will be voluntary, not generalizable, and will not be used for statistical purposes.

A.8.1 Comments in Response to the Federal Register Notice

The 60-day Federal Register Notice was published on February 14, 2023 (Vol. 88, pg. 9527) and allowed 60 days for public comment. No public comment was received.

A.8.2 Efforts to Consult Outside Agency

No outside consultation is intended

A.9 Explanation of Any Payment of Gift to Respondents

It is possible that some information collection activities will entail a small payment or gifts to respondents. The agency does not typically provide payment or other forms of remuneration to participants, however if it is necessary for hard to reach populations, details and a justification will be provided. Instances for offering an incentive will be determined on a case-by-case basis (depending on the particular information collection design).

A.10 Assurance of Confidentiality Provided to Respondents

Personal Identifiable Information (PII) will only be collected to the extent necessary. Respondents will be assured that neither their participation nor lack of participation will have any effect on their eligibility for receipt of services. In addition, respondents will be advised of the purpose of the information collection, the use of information collection, NIH sponsorship, that their participation is voluntary, and that they may choose to discontinue or have their name and/or related information withdrawn at any time. In instances where it is possible, information will be presented in an aggregate form without links to the identity of individual participants. The Privacy Act applies to the information collection per Privacy Act System of Records Notice (SORN) 09-25-0156, "Records of Participants in Programs and Respondents in Surveys Used to Evaluate Program of the Public Health Service, HHS/PHS/NIH/OD".

It may be necessary for some information collections to retain name and contact information to be used to contact potential respondents. In these instances, the rationale for retention of PII will be fully explained. Most of the information collections to be conducted under this clearance is considered exempt from Institutional Review Board (IRB) review at NIH. However, if it is determined that the information collection involves non-exempt activities, the staff will be required to submit the information collection for review to the IRB for approval.

A.11 Justification for Sensitive Questions

This generic will allow for sensitive questions specifically in the context of determining demographics and promoting diversity. NIH values diversity (NOT-OD 20-031) and inclusion,

and this data will assist NIH in being more inclusive of culturally, medically, and behaviorally sensitive matters. All questions of a sensitive nature will be justified. The justification will include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent. All sensitive questions will be voluntary fields.

A.12.1 Estimates of Hour Burden Including Annualized Hourly Costs

Participants in these activities may include research in academia or industry, clinicians, patients and patient's advocacy organizations, other non-governmental organizations, and members of the public. A variety of instruments and platforms will be used to collect information from respondents and each sub-study will vary by number of respondents and average time per response. However, the annual burden hours requested 18,601 is based on the number of collections we expect to conduct over the requested three-year period for this clearance.

Table 12-1 Estimated Annualized Burden Hours

Type of Collection	No. of Respondents	No. of Responses per Respondent	Time per Response (in hours)	Total Hours
Call for Nominations/Resources	1,000	1	10/60	167
Recommendations of scientific reviewers	1,000	1	5/60	83
Request for Population Characteristics	20,000	1	5/60	1,667
Repository of Tools and Best Practices	100,000	1	10/60	16,667
Total		122,000		18,584

A.12-2 ANNUAL COST TO RESPONDENT

These estimates are based on the following data from the Bureau of Labor Statistics: the General Public rate was obtained from the https://www.bls.gov/oes/2022/May/oes_nat.htm#00-0000

occupation title "All occupations" occupation code 00-0000. The Health Professionals wage rate was obtained from https://www.bls.gov/oes/2022/May/oes_nat.htm#00-0000 occupation title "Healthcare Practitioners and Technical Occupations", occupation code 29-0000; and the Health Educators wage rate was obtained from http://www.bls.gov/oes/current/oes211091.htm, occupation code 21-1091.

Table 12-2 Annualized Cost to Respondents

Type of Respondents	Total Annual Burden Hours	Hourly Respondent Wage Rate*	Respondent Cost
General Public	18,334	\$28.01	\$513,535.34
Health Professionals	83	\$43.80	\$3,635.40
Health Educators	167	\$31.22	\$5,213.74
TOTAL	18,584		\$522,384.48

^{*}Source of the mean Hourly Wage Rate is provided by the Bureau of Labor Statistics, Occupation title "All Occupations" 00-0000, https://www.bls.gov/oes/current/oes nat.htm#00-0000

A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no additional costs of than a respondent's time.

A.14 Annualized Cost to the Federal Government

The annual cost to the Federal Government for the proposed data collection effort is \$11,977.50

Cost Descriptions	Grade/Step	Salary*	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Program Analyst	GS 14/8	\$163,252	10%		\$16,325.20

Contractor Cost			
Travel			
Other Cost			
Total			\$16,325.20

^{*}the Salary in table above is cited from https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/18Tables/html/DCB.aspx

A.15 Explanation for Program Changes or Adjustments

This is an extension of currently approved request.

A.16 Plans for Tabulation and Publication and Project Time Schedule

The information collected through this collection is primarily for internal review and will not be published. However, for certain activities, information may be published on an NIH website or included in a printed or online program for the activity or subsequent publication describing the activity. Each project submitted under this generic clearance will specify plans for tabulation, timeline, and publication of the information collection.

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB control number and expiration date will be displayed.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

None